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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/376,430	08/18/99	MOORE	P PF466P1

HM22/0706

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1646	11

DATE MAILED: 07/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1- File Copy

U.S. G.P.O. 1999 460-693

Office Action Summary

Application No.	Applic(s)
09/376,430	Moore et al.
Examiner	**Group Art Unit**
Eileen B. O'Hara	1646

☒ Responsive to communication(s) filed on *Apr 17, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1, 13, 17-19, and 22-101* is/are pending in the applicat

Of the above, claim(s) *1, 13, 17-19, 22, and 23* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *24-101* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1, 13, 17-19, and 22-101* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Claims 1, 13, 17-19 and 22-101 are pending in the instant application. Claims 2-12, 14-16 and 20-21 have been canceled and claims 24-101 have been added as requested by Applicant in Paper Number 9, filed April 17, 2000.

Election/Restriction

2. Applicant's election with traverse of Group II in Paper No. 9 is acknowledged. The traversal is on the ground(s) that search and examination of the nine groups would not entail a serious burden . This is not found persuasive because consistent with current patent practice, a serious search burden may be established by (A) separate classification thereof: (B) a separate status in the art when they are classifiable together: (C) a different field of search:. These criteria were met in the above restriction. For example, a search for antibodies to a protein would constitute a different search than that of a search for the protein. It is old and well known in the art that antibodies have been generated without having purified protein, and antibodies to one protein may also cross-react with a related protein. As stated in the MPEP § 803, "a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02.". Further, a search is directed not only to art which would be anticipatory, but also to art that would render the invention obvious. Thus, the nine groups require divergent searches, and to search all inventions would be burdensome.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 13, 17-19, 22 and 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 24-101 will be examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 38 and 39 are indefinite because a heterodimer could comprise the polypeptide, but not the opposite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4.1 Claims 24-101 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Claims 24-101 are directed to isolated polypeptides comprising the amino acid sequence of SEQ ID NO:2, encoded by the polynucleotide comprising the nucleotide sequence of SEQ ID NO:1, deposited as clone HTAEK53 under Accession Nos. 209691 and 209491.

The instant specification discloses that the polypeptide comprising the amino acid sequence presented in SEQ ID NO:2 is a putative receptor molecule of the interleukin common gamma chain family, identified as Cytokine Receptor Common Gamma Chain Like or CRCGCL protein, based on homology to the cytokine receptor family and other common gamma chains. The closest homology is to the Bos taurus common gamma chain of IL-2 receptor, with which it has 7.9% overall similarity and 27.5% local similarity over a stretch of 254 amino acids. Because the clone was isolated from an activated T-cell cDNA library and Northern analysis showed that CRCGCL is expressed in HeLa cells, a lung carcinoma cell line, the lymph node and spleen tissues, it is asserted that CRCGCL could be important as a cytokine receptor and may be involved in the differentiation and proliferation of cells, and the tissue distribution of this gene in cells of the immune system suggests that the protein product of this clone would be useful for treatment, prophylaxis and diagnosis of various immune and autoimmune diseases which are listed on pages 10-11 and 97-106. There is no ligand identified that binds to it, no signaling pathway with which it is involved, and no disease or disorder correlated with the CRCGCL polypeptide.

The instant specification describes the uses and methods of the polypeptide, and asserts that the polypeptide regulates the differentiation and/or proliferation of cells, activates

proliferation or differentiation of immune cells, increases proliferation or differentiation of hematopoietic cells and modulates hemostatic activity and inflammation. However, because the specification does not provide adequate guidance as to the ability of the polypeptide to perform these activities or to the specific cell types that are modulated or activated, the claims are not enabled for these activities.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (FED. Cir. 1988).

It is acknowledged that the level of skill of those in the art is high. It is not disclosed and not predictable from the limited teachings of the prior art and specification that the polypeptide of the present invention would have any of the activities stated above. There is limited guidance as to which kinds of cells, for example, could be regulated as far as differentiation or proliferation. The specification does not provide any working examples that the polypeptide functions as recited in the claims, and limited guidance. It is not predictable, based on limited regions of homology to proteins with known functions, what activities the polypeptide of the invention has. Generally, the art acknowledges that function cannot be predicted based on structural information alone. For example, Bowie et al. (1990, Science 247:1306-1310) state that

determination of three dimensional structure from primary amino acid sequence, and the subsequent inference of detailed aspects of function from structure is extremely complex and unlikely to be solved in the near future (p. 1306). Thus, the specification fails to teach the skilled artisan how to use the claimed polypeptide without resorting to undue experimentation to determine what the specific biological activities of CRCGCL protein are. The specification has not provided the person of ordinary skill in the art the guidance necessary to be able to use the polypeptide for the above stated purposes.

Due to the large quantity of experimentation necessary to determine the specific activities of the polypeptide and the types of cells that would be affected, the lack of direction/guidance presented in the specification regarding same, the absence of working examples and the teachings of the prior art that protein function cannot be determined by structure and the complex nature of the invention, undue experimentation would be required of the skilled artisan to use the claimed invention. What Applicant has provided is a mere wish or plan and an invitation to experiment.

Even if the specification were fully enabling for the above activities and uses of CRCGCL protein, enablement would not be found to be commensurate in scope with the claims. The skilled artisan would not know what functions or activities polypeptides that are 90-95% identical to the polypeptides disclosed in the specification would retain, or polypeptides that can have from one to 30 amino acid substitutions to those polypeptides.

4.2 Claims 31-39, 51, 53, 59-63, 76-87, 94-99 and 101 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a

way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The enablement of claims 31-39, 51, 53, 59-63, 76-87, 94-99 and 101 requires availability of the specific clones claimed therein. This determination has been made because said clones are not fully disclosed nor have they been shown to be publicly known and freely available. Accordingly, it is deemed that a deposit containing these clones should have been made in accordance with MPEP Chapter 2400 and 37 C.F.R. §§ 1.801-1.809. The Examiner acknowledges the deposits accorded under ATCC Nos. 209691 and 209641 of clone HTAEK53 under terms of the Budapest Treaty (see page 5 of the specification). An affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 40, 43 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Sugamura et al., EP 0578 932 A2, Jan. 19, 1994.

Claims 40, 43 and 46 encompass an isolated polypeptide comprising an amino acid sequence comprising residues m to n of SEQ ID NO:2, where m is an integer in the range of +2 to +370 and n is an integer in the range of +2 to +371, and a composition comprising the polypeptide and a pharmaceutically acceptable carrier.

Sugamura et al. disclose a polypeptide (SEQ ID NO:4) comprising an amino acid sequence that is identical to amino acids 54-57 (m=54, n=57), 81-84 (m=81, n=84) and amino acids 150-153 (m=150, n=153) of SEQ ID NO:2 (amino acids 61-64, 90-93 and 165-168, respectively of SEQ ID NO:4), and a composition comprising the polypeptide and a pharmaceutically acceptable carrier (claim 34).

Therefore, Sugamura anticipates claims 40, 43 and 46.

Conclusion

6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D

Eileen B. O'Hara 6/28/00

Patent Examiner

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER